

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION**

WAVE NEUROSCIENCE, INC. a Delaware
Corporation,

Plaintiff,

vs.

BRAIN FREQUENCY LLC, a Texas Limited
Liability Company

Defendant.

Case No. 5:23-CV-00626-XR

Honorable: Xavier Rodriguez

MOTION FOR SUMMARY JUDGMENT OF INVALIDITY UNDER 35 U.S.C. §101

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Pursuant to Federal Rule of Civil Procedure 56, Defendant Brain Frequency LLC (“Brain”) brings this motion for summary judgment against Plaintiff Wave Neuroscience, Inc., (“Wave”) on the grounds that the asserted claims of U.S. Patent No. 8,926,490 (“490 Patent”), No. 8,465,408 (“408 Patent”), and No. 8,870,737 (“737 Patent”) (collectively, the “Asserted Patents”) are invalid under 35 U.S.C. § 101 as a matter of law.

I. INTRODUCTION

Each of the Asserted Patents purports to teach certain systems and methods for using Transcranial Magnetic Stimulation (“TMS”) to change the frequency of brainwaves by applying magnetic fields to the human brain. TMS, however, has been in research and therapeutic use for decades—long before the priority dates of the Asserted Patents. More importantly, their teachings—using magnetic fields to impact a person’s brain frequencies—are simply an application of the long recognized natural phenomenon of “brain entrainment.”

“Brain entrainment” has been known for nearly a hundred years, and was first described in 1934 in one of the first EEG reports by Adrian and Matthews (“Adrian and Matthews 1934”). *Id.* ¶ 6. Adrian and Matthews successfully demonstrated that the frequency measured by an EEG in the visual cortex of a human brain could be “entrained” to the frequency of a visual flicker applied externally. *Id.*

The Asserted Patents are exceedingly broad and do not claim anything specific other than the naturally occurring phenomenon of brain frequency shifting when a magnetic field is applied. The Asserted Patents thus claim a natural phenomenon that is not—and should not be—patentable pursuant to 35 U.S.C. § 101. *See Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 217 (2014); *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 566 U.S. 66, 70 (2012).

Wave invented neither the concept of brain entrainment nor TMS, and its effort to monopolize this medical field—without having discovered anything new or inventive to warrant

patent protection—is precisely the kind of misuse of patent laws that the Supreme Court and the Federal Circuit have repeatedly rejected.

II. WAVE’S RELATED AND SUBSTANTIALY SIMILAR PATENTS PREVIOUSLY INVALIDATED BY THE SOUTHERN DISTRICT OF CALIFORNIA

Wave has asserted substantially similar and related patents in another lawsuit: *Wave Neuroscience, Inc. v. PeakLogic, Inc. and Keven T. Murphy M.D.*, Case No. 2-cv-1330-CAB-SBC in the U.S. District Court for the S.D. of Cal. (“*PeakLogic*”). In *PeakLogic*, all three patents asserted by Wave were found to be aimed at brain entrainment, and two of Wave’s patents, U.S. Patent Nos. 8,480,554 (“’554 Patent”) and 9,446,259 (“’259 Patent”) were invalidated under §101. [Order of Invalidity, *PeakLogic* (Dkt. 55-1)]. *Id.*, Dkt. 261 (later vacated on procedural grounds (*id.*, Dkt. 284) due to settlement and dismissal *with prejudice* (*id.*, Dkt. 288))).¹ The finding in *PeakLogic* directly applies here because the claims of the invalidated patents are substantially similar to the Asserted Patents here. Indeed, they are in the same patent family: the asserted ’490 Patent is a continuation-in-part of the invalidated ’554 Patent, and the asserted ’737 Patent claims priority from the same provisional application (61/260,779) as the invalidated ’259 Patent. Wave’s procedural maneuver in *PeakLogic* does not alter the solid substantive §101 analysis by the *PeakLogic* court.

¹ On Nov. 20, 2024, the *PeakLogic* parties jointly moved to vacate the Order on invalidity as part of settlement: “The Parties have now agreed to settle this case, but the settlement is specifically conditioned on the Court vacating its prior invalidity ruling. Thus, the requested vacatur is a critical factor to successfully resolving the litigation. If the order is not vacated, the Parties will, unfortunately, be forced to continue with the lawsuit through the end of trial (wasting considerable time and money in the process).” Joint Motion to Vacate (Dkt. 269) at 2 (“As evidence of the potential significant impact to Wave of the Invalidity Order, in a lawsuit against a different defendant currently pending in the Western District of Texas (which involves at least one patent related to the Asserted Patents), the defendant has already relied upon the Invalidity Order in the context of claim construction and threatened to file a summary judgement motion for invalidity based, at least in part, thereon. If not vacated, other courts could also rely on the reasoning of the Invalidity Order to collaterally estop Wave from asserting the ’554 and ’259 Patents.”)

III. FACTUAL BACKGROUND

The technological background set forth by defendant *PeakLogic* is accurate and relevant. It is incorporated fully herein by reference, and is reproduced in relevant part below.

A. The Science of TMS and Brainwave Entrainment

1. Repetitive Transcranial Magnetic Stimulation (“rTMS”)

TMS is a non-invasive method of affecting the brain which is accomplished through pulses of magnetic fields passing through the cranium. *See* Declaration of Jarod Dempsey, PhD (“Dempsey Dec.”) at ¶10. TMS has been used as research and therapeutic technique since 1985. Dempsey Dec. at ¶11. While TMS was originally administered as a single pulse, in the early 1990s, multiple pulses began to be administered in repeated bursts. Repeated pulses became known as “rapid” or “repetitive” TMS, or rTMS. *Id.* at ¶14. The goal of TMS and rTMS has been to treat or provide relief from certain symptoms, and to improve cognitive function. *Id.* ¶14. rTMS has been used to treat depression and schizophrenia since at least 1997. *Id.* at ¶17.

In practice, all or nearly all TMS machines use electromagnets. *Id.* at ¶11. The magnets must be placed directly on, or within a few inches of, the head of a subject, because the strength of the magnetic field decays proportionally to the square of the distance from the source. *Id.* The application of electronic magnetic fields (“EMFs”) to the brain and assessment of changes by Electroencephalography (“EEG”), a method used to record the spontaneous electrical activity of the brain, have been extensively described since the 1970s. *Id.* at ¶13. In addition, the use of magnetic fields with strengths in the range described by the patents at issue (10 Gauss to 4 Tesla) was widely known and in common use prior to the priority date of the patents. *Id.* at ¶12; *see also, e.g.*, ’490 Patent at 3:11-12; ’737 Patent at 3:9-10; ’408 Patent at 6:13-15 (each referencing 10 Gauss to 4 Tesla).

Existing rTMS machines sold in the United States before the priority date of the Asserted Patents used processors to control the firing of the magnetic field. Dempsey Dec. at ¶36. For example, the MagVenture R30, which was sold by 2006 and is still in use, contains a processor which allowed the user to set and administer various frequencies and other characteristics of rTMS therapy on the machine itself. *Id.* The MagVenture R30 is also configured with a data port which allows it to be controlled by an external computer or processor. *Id.*

2. *EEG and Intrinsic Frequencies*

EEG technology has been used with TMS for decades as well. Signals measured using EEG are commonly known as “brainwaves” which occur in various frequencies. In humans, brainwaves are typically categorized by the frequency bands in which they occur, including for example the alpha frequency band (7.5-12.5 Hz). *Id.* at ¶22. An EEG device simply identifies the peak signal power in a given band. For example, Peak Alpha Frequency (“PAF”) refers to the frequency at which the alpha rhythm oscillates over a given period. *Id.* at ¶21. In the Asserted Patents, this is defined as “intrinsic frequency” or the “frequency at which peak signal power is located.” Thus, this concept has existed for years prior to the Asserted Patents.

Taking the EEG of a patient before and after a patient undergoes TMS therapy was also well known at the time of the patent applications. Dempsey Dec. at ¶¶19, 20 (*citing* Adrian and Matthews 1934 report, studies on electromagnetic fields and their effects of EEG parameters from the 1970s, the 2005 study authored by Yi Jin (the co-inventor of the patents-in-suit) titled *Therapeutic Effects of Individualized Alpha frequency Transcranial Magnetic Stimulation (aTMS) on the Negative Symptoms of Schizophrenia*, October 26, 2005 Schizophrenia Bulletin (“Jin-2005”). Thus, *Jin-2005*, for example, teaches the process of adjusting the administered frequency in response to EEG measurements taken after the patient undergoes rTMS. *Id.*

3. *Brainwave Entrainment*

Brainwave entrainment refers to the observation that brainwaves will naturally synchronize to the rhythm of periodic external stimuli. Dempsey Dec. at ¶9. Thus, if the intrinsic frequency of the subject is at a particular frequency (f_1), and a stimulation is applied at a different frequency (f_2), entrainment will cause the intrinsic frequency to move in the direction of f_2 . *Id.* Entrainment is simply the natural response of the human body to external stimulation. *Id.* at ¶29. This natural phenomenon has been well known for decades, at least as early as the 1934 Adrian and Mathews report. *Id.* at ¶¶9, 19, and 24 (*citing* Will & Berg).

rTMS was known to cause brainwave entrainment years before the priority dates of the patents in suit. Dempsey Dec. at ¶24. For example, in 2001, researchers published scientific evidence showing that when rTMS at 10 Hz was applied to a subject whose PAF (measured via EEG) was less than 10 Hz, the PAF of the subject rose to 10 Hz or more. *Id.* ¶¶ 24–26. Other studies have confirmed the same results. *Id.* at ¶¶ 27, 28. It is thus an established scientific fact that when rTMS is administered to the brain of a subject, the subject’s intrinsic frequency moves to the frequency of the rTMS administered. *Id.* That conclusion is not limited to changing a subject’s intrinsic frequency—it extends to other characteristics of the subject’s brainwaves, such as the EEG phase (*Id.* at ¶29), Q-Factor (*Id.* at ¶31), or coherence value (*Id.* at ¶24).

4. *TMS and Q-Factor*

In addition to manipulating an intrinsic frequency, some claims of the Asserted Patents also involve use of a Q-factor—which is simply the “ratio of the intrinsic frequency relative to the frequency bandwidth at half peak energy.” Dkt. 59 at 18. Since the Q-factor relates—by definition—directly to its intrinsic frequency, changes in “Q-factor” are also the product of the natural phenomenon of brain entrainment. As entrainment of the brainwaves is achieved, the amplitude (or “power”) of the entrained frequency increases, and the width of the brainwave (Δf

at $E_{max} / 2$) generally decreases due to the effect of the synchronized alpha waves, resulting in an increase in the “Q-factor.” Dempsey Dec. ¶ 34.

IV. PROCEDURAL BACKGROUND

Wave asserts Claims 1 and 9 of the ’490 Patent, Claims 1-4, 9, 10, 12, and 20 of the ’408 Patent, and Claims 1-4, 8, 9, and 11 of the ’737 Patent.²

On November 12, 2024, following briefing and a Markman hearing, the Court issued its Claim Construction Order. (Dkt. 59). The Claim Construction Order broadly construed the following disputed claims:

Term	Construction
“intrinsic frequency”	“frequency at which peak signal power is located to which treatment is to be applied”
“in-phase/in phase”	“waveforms whose peaks and troughs occur at substantially the same time”
“out of phase”	“waveforms whose peaks and troughs do not occur at substantially the same time”
“Q-Factor”	“ratio of the intrinsic frequency relative to the frequency bandwidth at half peak energy”
“coherence value”	“a measure of similarity between two or more signals over time”
“close to the head”	“wherein the head is not outside the magnetic field”

Dkt. 59 at 18. The Court further adopted nine agreed constructions. *Id.* at 18–19.

V. LEGAL STANDARD

A. Summary Judgment

“Patent eligibility under 35 U.S.C. § 101 is a question of law.” *Genetic Techs. Ltd. v. Meril L.L.C.*, 818 F.3d 1369, 1373 (Fed. Cir. 2016). Whether something is well-understood, routine, and conventional is a factual question (*Berkheimer v. HP Inc.*, 881 F.3d 1360, 1369 (Fed. Cir. 2018)), but summary judgment is appropriate where there is no genuine dispute of

² Wave originally asserted four patents against Brain, but has dropped one patent.

material fact as to that question. *Mortg. Grader, Inc. v. First Choice Loan Servs. Inc.*, 811 F.3d 1314, 1325-26 (Fed. Cir. 2016) (affirming grant of summary judgment of patent ineligibility under Section 101); *Accenture Global Servs., GmbH v. Guidewire Software, Inc.*, 728 F.3d 1336, 1346 (Fed. Cir. 2013) (same).

B. Patentable Subject Matter

“[L]aws of nature, natural phenomena, and abstract ideas are not patentable.” *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 566 U.S. 66, 70 (2012) (quotation marks omitted). Only “innovative” or inventive uses of natural phenomena are afforded patent protection. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 595 (2013). This restriction on patentability derives from “a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature.” *Mayo*, 566 U.S. at 85. The prohibitions on patenting laws of nature, natural phenomena, and abstract ideas “exist because monopolizing the basic tools of scientific work ‘might tend to impede innovation more than it would tend to promote it.’” *CareDx, Inc. v. Natera, Inc.*, 40 F.4th 1371, 1376 (Fed. Cir. 2022) (quoting *Mayo*, 566 U.S. at 71); see also *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015) (“patent claims should not prevent the use of the basic building blocks of technology—abstract ideas, naturally occurring phenomena, and natural laws”).

In determining whether patents claiming natural phenomena are eligible for protection under 35 U.S.C. § 101, the court undertakes a two-step inquiry, asking: (1) whether the patent is directed to the natural phenomenon; and then, if so, (2) whether the claims recite an inventive concept “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.” *Mayo*, 566 U.S. at 72-73, 77-80; see also *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 217-18 (2014).

“The prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of the formula to a particular technological environment or adding insignificant post solution activity.” *Mayo*, 566 U.S. at 73. Accordingly, “simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable.” *Id.* at 82.

VI. THE PATENTS-IN-SUIT CLAIM INELIGIBLE SUBJECT MATTER

As stated, the Asserted Patents are substantially similar and related to the two patents that were invalidated in the PeakLogic case. Indeed, the *PeakLogic* Court properly recognized that *all* three challenged patents were directed towards a natural phenomena:

[A] brain’s inherent electrical frequency can be altered by exposure to a magnetic field of a different higher or lower frequency....Other than claiming an EEG is used to determine the intrinsic frequency of the subject’s brain, a known and conventional use of an EEG, there are no limitations as to how a magnetic field of a higher or lower frequency is selected, generated, or applied to the subject’s head.

[PeakLogic Order at 6]. As shown below, the Asserted Patents in this matter, which are substantially similar to and in the same patent family as the invalidated patents, are also all directed towards the natural phenomenon of brainwave entrainment.

A. Step 1: The Asserted Claims Are Directed to a Natural Phenomenon

It is undisputed that each living person has an intrinsic brain frequency. Dempsey Dec. at ¶8. Plaintiff’s expert Dr. Bikson agrees. Dkt. 32-5, ¶61 (“Each subject has their own internal, *i.e.* intrinsic, frequency which can be measured by an EEG.”) (“Bikson Dec.”) It is also beyond dispute that brainwave entrainment—the fact that the frequency of brainwaves naturally changes in response to external magnetic fields (such as rTMS) in an attempt to match the frequency of the stimulation—is a known natural phenomenon. Dempsey Dec. at ¶24. This has been known as early as the 1934 Adrian and Mathews report. *Id.* at ¶¶9, 19.

Wave did not invent and cannot claim patent protection over the natural phenomenon of brainwave entrainment through rTMS. *Mayo* at 70. While the human activity of applying electromagnets to the brain intentionally triggers this manifestation in a particular subject, the relationship between external stimuli and brainwaves exists apart from any human action. *Dempsey* Dec. at ¶9. Just as in *Mayo*, the fact that human action triggers a natural response does not take claims outside the prohibition on patentability of natural phenomena:

[Plaintiff's] patents set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm. . . . While it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.

Mayo, 566 U.S. at 77. Claiming a patent on a natural phenomenon such as this is impermissible.

1. The '737 Patent (claims 1 – 4, 8, 9, and 11)

The priority date of the '737 Patent is Nov. 12, 2009. Plaintiff asserts Claims 1–4 and 8, 9, and 11 of the '737 Patent, which are all method claims. *See* Appx. A.A. All asserted claims are methods inherently directed to the natural phenomenon of brainwave entrainment through the use of TMS and are thus ineligible for patent protection under *Alice/Mayo*.

Claims 1 and 2, the only independent claims, recite “adjusting output of a magnetic field” and thereby “moving, using the magnetic field” “an intrinsic frequency of a specified EEG band of the subject toward a pre-selected intrinsic frequency of the specified EEG band” or, for claim 1 only, “a Q-factor of an intrinsic frequency within a specified EEG band of the subject toward a pre-selected Q-factor.” This effectively claims the natural phenomenon of brainwave entrainment. *Dempsey* Dec. at ¶¶39, 40.

Claims 1 and 2 go on to recite applying the output of the magnetic field close to the head of a subject, which is inherent in rTMS treatment. *Id.* at ¶¶10, 40.

The claims further lists the automatic known effects of that movement of the intrinsic frequency and related Q-Factor: “wherein the pre-selected intrinsic frequency is a frequency that increases (claim 1) or decreases (claim 2) blood flow in the cortex of the subject” and, for claim 1 only, “wherein the pre-selected Q-factor is a Q-factor that increases blood flow in the cortex of the subject.” The claim language explicitly only observes a known effect, that is increasing the intrinsic frequency (or Q-Factor) to increase blood flow in the cortex of the subject (claim 1), or decreasing the intrinsic frequency to decrease blood flow (claim 2). *Id.* at ¶44. Between the two claims, they claim all possible outcomes of applying any kind of magnetic field to the head of a subject, *i.e.*, either increasing or decreasing the intrinsic frequency (and thereby the Q-Factor, which is defined using the intrinsic frequency). *Id.* Allowing Plaintiff to monopolize this basic scientific principal would undoubtedly “tend to impede innovation more than it would tend to promote it.” *CareDx.*, 40 F.4th at 1376 (*quoting Mayo*, 566 U.S. at 71).

Pre-selecting a frequency for treatment, or a target frequency, was well known in the art. Dempsey Dec. at ¶41 (citing *Yin-2005* and *Klimesch-2003*). First, TMS devices inherently require setting a frequency to operate at before the machine is activated to administer therapy to the patient. This is specifically disclosed in *Yin-2005*, which discloses “that [an] EEG was taken before the rTMS treatment and that the treatment frequency was individualized based on the EEG results.” *Id.* (citing *Yin-2005* at pg. 557 (“The frequencies for the active stimuli were 3 Hz, individualized alpha (8–13 Hz) and 20 Hz. Rate for the alpha frequency stimulation was determined at the nearest integer of each patient’s average alpha peak frequency, obtained from 5 frontal EEG leads (F7, F3, Fz, F4, F8).” (emphasis added))). Dr. Dempsey further explains that

this technique was also disclosed in *Klimesch-2003* which “initially measured the subject’s intrinsic alpha frequency (‘IAF’) using EEG and then administered rTMS therapy at a ‘pre-selected / target frequency’ of that measured frequency + 1 Hz.” *Id.* at ¶41 (citing *Klimesch-2003* at 1132 (page 4 of PDF)). Thus, rTMS was known and administered at “pre-selected frequencies in the alpha band or sub-bands near IAF.” *Id.* Thus, using an EEG to determine a patient’s intrinsic frequency, and pre-selecting a frequency based on that measurement to use during treatment was well known in the art.

Notably, the Court construed the term “intrinsic frequency” as ““frequency at which peak signal power is located to which treatment is to be applied,” thus confirming that the patient’s average alpha peak frequency is referred to as the “intrinsic frequency. Dkt. 59 at 18.

Indeed, the Asserted Patents specifically refer to using the average of multiple EEG leads to defining the patients’ intrinsic frequency. *See, e.g.*, ’408 Patent at 51:44-49. “EEG data during treatments are recorded and individualized according to the alpha EEG intrinsic frequency (8-13 Hz). The precision of the stimulus rate can be refined to the level of 10% of a hertz. It is determined on each patients average alpha frequency, obtained from 3 central EEG leads (C3, C4, and Cz).”; *see also* ’490 Patent at 69:5-10 and ’737 Patent at 63:65-64:3.

The remaining dependent claims (3, 4, 8, 9, and 11) do not change this analysis and only add trivial known building blocks. Claim 3 adds taking an EEG measurement before and/or after applying the magnetic field to monitor the intrinsic frequency / Q-Factor. This was known. *Id.* at ¶46. “Claim 4 adds ‘determining’ the intrinsic frequency or Q-Factor, which is inherent in claims 1 and 2 to detect movement thereof.” *Id.* “Claim 8 adds the time period of applying the field, which was known.” *Id.* “Claim 9 adds repeating the process, which was also known.” *Id.* Claim 11 adds increasing the HAMD score through rTMS, which was known. *Id.* The

dependent claims do nothing more than recite “well understood, conventional and routine” steps known in the application of rTMS and thus lack the inventive concept necessary for patent eligibility. *CareDx, Inc.*, 40 F.4th at 1380 (“applying standard techniques in a standard way to observe natural phenomena does not provide an inventive concept.”).

2. *The '408 Patent (claims 1 – 4, 9, 10, 12, and 20)*

The priority date of the '408 Patent is Aug. 6, 2009. Independent claim 1 and its dependent claims 2, 3, 4, 9, and 10 are method claims. Independent claim 12 and its dependent claim 20 are system claims that effectively mirror the method claims. All asserted claims are inherently directed to the natural phenomenon of brainwave entrainment through the use of TMS and are thus ineligible for patent protection under *Alice/Mayo*.

Method Claims:

Claim 1, an independent method claim, is even more broad than independent claims 1 and 2 of the '737 Patent, and claims only treating various conditions by “adjusting a setting of a magnetic field” such that it is configured to effect moving one or more of an intrinsic frequency, a Q-Factor, a coherence value, or an EEG phase, and then applying said magnetic field. This is literally simply brainwave entrainment. Dempsey Dec. at ¶48.

The claimed EEG phase “is another characteristic of brainwaves which is naturally entrained by the external stimulation of rTMS), like intrinsic frequency and Q-factor. “ Dempsey Dec. at ¶¶49. Claim 1’s limitation “wherein the magnetic field comprises one or more magnetic field generators that are of the same frequency and are in-phase with each other, of the same frequency and out of phase with each other, or a combination thereof” adds nothing new. *Id.* at 49¶. Any two signals that are of the same frequency, whether they are magnetic fields, light waves, or audio waves, are necessarily “in-phase with each other, out of phase with each other, or a combination thereof.” *Id.* Applying two magnetic fields at the same frequency to the head

of a subject in rTMS was well known prior to the priority date of the Asserted Patents. *Id.* The claims reference to matching the phase and frequency as “coherence value” does not change this natural concept. *Id.*

Further, the elements to be moved (“intrinsic frequency,” “Q-Factor,” “coherence value,” “EEG phase,” “or a combination thereof”) are limiting only in the alternative—the claim requires moving only “one or more” of them. As explained by Dr. Dempsey, “these alternative elements are simply other aspects of the natural law of brainwave entrainment: when an external rhythmic stimulation is administered to the human brain, the brainwaves will become entrained, in frequency and phase. As a result, the Q-factor (as defined by the Asserted Patents) will necessarily change as a result of the synchronization of the brain’s alpha rhythms with frequency of rTMS.” Dempsey Dec. at ¶50.

Similarly, claim 2 recites treating various conditions by “moving” an intrinsic frequency or Q-Factor “by applying a magnetic field close to a head of the subject,” where the magnetic field comprises a single target frequency, or a plurality of frequencies, or the intrinsic frequency—in other words, any frequency or combination of frequencies. Both claims again effectively claim only the natural phenomenon of brainwave entrainment. Dempsey Dec. at ¶52. (subjecting the human brain to a magnetic field inherently causes brain entrainment).

As explained above, pre-selecting a frequency for treatment, or a target frequency, was well known in the art. Dempsey Dec. at ¶41 (citing *Yin-2005* and *Klimesch-2003*). Thus, using an EEG to determine a patient’s intrinsic frequency, and pre-selecting a frequency based on that measurement to use during treatment was well known in the art.

Dependent claims (3, 4, 9, and 10)—like those of the ’737 patent—do not change this analysis and only add trivial known building blocks. Claim 3 adds taking an EEG measurement

before and/or after applying the magnetic field to monitor the intrinsic frequency / Q-Factor. This was known in the art. Dempsey Dec. at ¶54. Claim 4 adds adjusting the magnetic field based on the EEG, which was known. *Id.* Claim 9 adds the time period of applying the field, which was known. *Id.* Claim 10 adds repeating the process, which was also known. *Id.* As in the '737 Patent, the dependent claims only add “well understood, conventional, and routine” steps and thus lack a patentable inventive concept. *CareDx, Inc.*, 40 F.4th at 1380.

System claims:

Independent system claim 12 adds nothing more than use of a computer system comprising known components to implement the method of claim 1. *Compare* '408 Patent, claim 12 with Claim 1. “The system components add nothing novel to the claimed invention, and literally serve only to implement the method of claim 1, which in turn comprises only the natural phenomenon of brainwave entrainment” using a magnetic field as explained above. Dempsey Dec. at ¶55.

Dependent system Claim 20 only adds logic able to determine the intrinsic frequency or Q-Factor from the EEG data. No inventive components are claimed that might warrant patent protection. Dempsey Dec. at ¶56.

3. *The '490 Patent (claims 1 and 9)*

The priority date of the '490 Patent is no earlier than September 24, 2008. Only independent system claims 1 and 9 are asserted. All asserted claims are systems inherently directed to the natural phenomenon of brainwave entrainment through the use of TMS and are thus ineligible for patent protection under *Alice/Mayo*.

Independent Claim 1 claims the natural phenomenon of brainwave entrainment using rTMS to treat depression. Dempsey Dec. at ¶57. It first recites “a magnetic field generator adapted to apply a magnetic field to a head of the subject.” This is inherent in rTMS treatment.

Id. Claim 1 further recites that the “magnetic field generator comprises a “non-transitory computer readable medium” and a processor, both components known in the art. The non-transitory computer readable medium stores a “subject data value” which comprising an intrinsic frequency, a Q-factor, a coherence value between two intrinsic frequencies from two different sites in the brain, or an EEG phase between two different sites in the brain. The EEG phase is another characteristic of brainwaves which is naturally entrained by the external stimulation of rTMS), like intrinsic frequency and Q-factor. *Id.* The processor controls the magnetic field to “move the first intrinsic frequency in a pre-selected direction, up or down,” “move the Q-factor of the first intrinsic frequency in a pre-selected direction, up or down”, “move the coherence value” or “move the EEG phase of the specified EEG frequency.” This claim thus also claims the natural phenomenon of brainwave entrainment.

The claim further lists the automatic known effects of that movement of the intrinsic frequency and related Q-Factor: “wherein the magnetic field increases the blood flow of a cortex of the brain or decreases the blood flow of a lower region of the brain.” Dempsey Dec. at ¶58 (*citing* ’490 Patent, claim 1). The claim language explicitly only observes a known effect, that is that changes in the magnetic field affects the blood flow in the region of the brain to which it is applied. *Id.* at ¶58.

As explained above, pre-selecting a frequency for treatment, or a target frequency, was well known in the art. Dempsey Dec. at ¶41 (*citing Yin-2005 and Klimesch-2003*). Thus, using an EEG to determine a patient’s intrinsic frequency, and pre-selecting a frequency based on that measurement to use during treatment was well known in the art.

Dependent Claim 9 only adds standard computer logic to “calculate the subject data value from EEG data” without disclosing how to do so. *Id.* at ¶59. This merely implements a known method on known standard computer logic. *Id.*

4. *Step 1 Summary:*

In summary, each of the Asserted Patents is directed to the use of a natural law. Each does no more than improperly claim the result of that natural law, without specifying any novel technological improvement to achieve that result. As courts have repeatedly held, such claims fail under *Alice/Mayo* step 1. See *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1167 (Fed. Cir. 2018) (holding that, to avoid ineligibility, a claim must “ha[ve] the specificity required to transform [the] claim from one claiming only a result to one claiming a way of achieving it”); *Apple, Inc. v. Ameranth, Inc.*, 842 F.3d 1229, 1244 (Fed. Cir. 2016) (claim that “calls for the desired result . . . and does not attempt to claim any method for achieving that result” is ineligible for patenting).

Indeed, the controlling decision in *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 967 F.3d 1285, 1294 (Fed. Cir. 2020) confirms that the patents here are directed to a natural phenomenon under *Alice/Mayo* step 1. There, the claim at issue was directed to a method for manufacturing driveline propeller shafts with liners, but the patent did nothing more than claim use of a law of physics and “describe[] the desired result.” *Am. Axle & Mfg., Inc.*, 967 F.3d at 1294. The claim did not “specify how target frequencies are determined or how, using that information, liners are tuned to attenuate two different vibration modes simultaneously.” *Id.* at 1298. Instead, the claim “simply instruct[ed] the reader to tune the liner to achieve a claimed result, without limitation to particular ways to do so.” *Id.*

The same is true here. The asserted claims simply describe a desired result—treating a mental health condition or other brain dysfunction—by moving brain characteristics “either up or

down” without describing a method of achieving that result. The asserted claims set forth no particular frequencies or ways to determine frequencies, magnetic field strengths, durations, or other aspects of treatment protocols. The Asserted Patents are devoid of any detailed formula as to how to actually achieve the desired results. They instead broadly claim the idea of using TMS to move the intrinsic frequency (or “Q-factor” or “coherence value” or “EEG phase”) of a subject’s brain to a higher or lower frequency. Far from claiming a specific value for one of these characteristics, the Asserted Patents leave it open to the user to determine what the “preselected intrinsic frequency” or “Q-Factor” should be. They only generally disclose that it *may be* “a harmonic of the peak intrinsic frequency,” it *may be* simply a ‘target frequency’ of the alpha band, it *may be* based on a healthy population, or it *may be* based on a “control group” of at least two people without regard to a ‘healthy population’.” *See, e.g.*, ’490 Patent at 15:48–58 (harmonic), 15:26–37 (healthy population), 65:65–66:5 (control group); ’737 Patent at 15:33–43 (harmonic), 17:1–3 (healthy population), 65:65–66:5 (control group); ’408 Patent at 11:61–12:3 (harmonic), 48:15–20 (control group). In short, no definite guidance is provided.

All Asserted Claims are directed to the same basic broad concept—using TMS to change brain characteristics—without providing limitations or meaningful guidance on *how to achieve the desired results*. The patents do not claim a specific roadmap to treat conditions with rTMS, such as with details on head positions, stimulation frequencies, amplitudes for certain diseases, or other particulars that could teach a user how to replicate (or avoid replicating) the method or device. Instead, they purport to preempt the entire natural phenomenon of neural entrainment using rTMS, such that no rTMS practitioner can help but run afoul of the patents’ claims. The Asserted Patents are thus directed to a natural phenomenon under *Alice/Mayo* step 1.

B. Step 2: The Asserted Claims Offer No Inventive Concept

Under the second step of *Alice/Mayo*, to survive a challenge under 35 U.S.C. § 101, the asserted patents must contain an “inventive concept sufficient to transform [the claimed abstract idea] into a patent-eligible application.” *RecogniCorp, LLC v. Nintendo Co.*, 855 F.3d 1322, 1327 (Fed. Cir. 2017) (quotation marks omitted). Step 2 of the analysis involves a “search for an inventive concept,” *i.e.*, “an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.” *Alice*, 573 U.S. at 217-18. Where the patent does nothing more than recite “well understood, conventional and routine” steps, it lacks the inventive concept necessary for patent eligibility. *Ariosa Diagnostics, Inc.*, 788 F.3d at 1377; *CareDx, Inc.*, 40 F.4th at 1380 (“We have repeatedly held that applying standard techniques in a standard way to observe natural phenomena does not provide an inventive concept.”).

1. The Asserted Method Claims

TMS technology was well-understood, routine, and conventional at the time the patents-in-suit applications were filed. TMS has been in use as a research and therapeutic technique since 1985. *Dempsey Dec.* at ¶14. This is undisputed. The technique of rTMS, administering rapid or repeated pulses, began to be used in the 1990s. *Id.* Moreover, rTMS was proven to entrain brain frequencies years before the priority date of the Asserted Patents. For example, in a 2001 study, evidence showed that when rTMS at 10 Hz was applied to a subject whose PAF (measured by an EEG) was less than 10 Hz, the PAF of the subject rose to 10 Hz or more. *Id.* at ¶¶24, 25. Thus, the use of rTMS technology for brainwave entrainment was well-understood, routine, and conventional prior to the date of the patent applications.

The limitations of the asserted claims were also well-understood, routine and conventional prior to the date of the patents-in-suit's applications, and none provides an inventive concept that could render the claims patent eligible.

First, the characteristics to be “moved” by rTMS under the Asserted Patents are merely examples of the natural phenomenon of neurological entrainment. As *PeakLogic* explained: the “claim instructs that application of an external magnetic field of a frequency different than the patient’s intrinsic frequency will move that intrinsic frequency.... *but provides no parameters as to how to achieve that result.*” [PeakLogic Order at 6].

It was well-known that rTMS would increase or decrease the “alpha” frequency prior to the application of the patents-in-suit. Dempsey Dec. ¶¶ 26-32. As explained in *PeakLogic*:

The Court further finds in the context of this claim, there is no inventive concept disclosed in the method. The steps simply tell a practitioner to determine the patient’s intrinsic frequency, determine a magnetic field of a higher or lower frequency and then apply it. The claimed result that it will improve a patient’s brain function may be the natural result of altering the patient’s brain frequency, but the claim provides no particular formula or instruction to achieve the result.

PeakLogic Order at 7.

While the asserted claims also claim to “move” or “tune” the “Q-factor”, the Q-factor concept adds nothing meaningful or new. As noted above, changes in alpha frequency inherently mean corresponding changes in Q-factor, and changes in Q-factor are nothing more than the inherent byproduct of the natural phenomenon of neural entrainment. Dempsey Dec. at ¶¶ 33-36. Moreover, the Q-factor concept was also disclosed before the Asserted Patents by one of the inventors, Yi Jin, in 2005. Dempsey Dec. ¶35 (citing Exs. 29). Likewise, the asserted claims substitute “EEG phase” for “intrinsic frequency” as the brain characteristic to be “moved” or “tuned” by rTMS technology. This is just another example of the natural phenomenon of neurological entrainment. *Id.* at ¶29. Thus, the substitution of “Qfactor” or “EEG phase” as the

brain characteristic to be “moved” or “tuned” adds no new inventive concept to the natural phenomenon of entrainment. Again, PeakLogic came to the same conclusion:

The steps simply tell a practitioner to determine the subject’s intrinsic frequency or phase, determine a different frequency or phase and adjust a magnetic field to that alternative frequency or phase and then apply it. That the subject’s intrinsic frequency or phase will move in response to the external stimuli is a natural physiological response. As a method to treat depression, the claims provide no particular formula or instruction to achieve the result. The claims are overly broad, and the Court finds they claim ineligible subject matter and are invalid.

PeakLogic at 8.

Second, the use of EEG technology in administering TMS was well-understood years before the priority date of the patents-in-suit. Dempsey Dec. at ¶¶14-20 (discussing *Klimesch-2003* (Ex. 16) and *Jin-2005* (Ex. 18)). Taking an EEG and measuring the frequency of a person’s brain and then adjusting that frequency up or down was known. As discussed by Dr. Dempsey, “[t]aking the EEG of a patient before and after the patient undergoes TMS therapy . . . was well known at the time of the Asserted Patents.” Dempsey Dec. at ¶19, 20. The *Jin-2005* study, for example, reveals that the patent’s EEG was taken prior to the first treatment and during the study. *Id.* Thus, the process of adjusting the administered frequency in response to EEG measurements was not a novel concept at the time of the applications of the asserted patents.

Third, placing the magnetic field close to the head of the subject adds no new inventive concept. With TMS technology, it is common practice to place the magnet or magnetic coil as close as possible to the head of the patient, if not in direct contact, because of the physics of magnetic fields. Dempsey Dec. at ¶11. Thus, the Asserted Claims’ step of placing the magnetic field “close to the head of the subject” was well-understood, routine and conventional on the priority date of the patents-in-suit. This step adds no new inventive concept that could salvage the patents under Section 101.

Fourth, the use of magnetic fields with the strength in the range described by the patents was well-understood, routine and conventional at the time the patent applications were filed. Dempsey Dec. at ¶12 (*citing* Ex. 18 (“*Jin-2005*”)). The particular strength range of the magnetic fields adds no new inventive concept. Indeed, as PeakLogic found: “There is no limitation or specifics regarding the selection of a target frequency or phase, *or the placement of the magnetic field other than ‘close to the head of the subject’ such that it will treat depression.*” *PeakLogic* at 8 (emphasis added).

Finally, the maladies aimed to be treated by the asserted claims do not add an inventive concept. The fact that rTMS therapy could be applied to provide relief from certain disorders, symptoms, and mental illness was well-understood, routine and conventional at the time of the application of the Asserted Patents. Dempsey Dec. at ¶17. Indeed, rTMS therapy has been used to treat depression and schizophrenia since at least 1997. *Id.* Thus, the asserted claims contain no inventive concept regarding illnesses to be treated with rTMS technology.

2. *The Asserted System Claims*

The asserted system claims similarly add no new inventive concept. Based on the plain language of the patents, the system claims recite only a device for generating a magnetic field without citing any specialized technical components or features not already known. They rely on standard components. Indeed, the only technical components referenced are “magnet”, “computer storage,” and “processor, but the specification describes none of these as novel or specialized. Indeed, the specification acknowledges that any magnets may be used. *See, e.g.*, ’490 Patent at 48:33-44; ’737 patent at 43:23-34; and ’408 Patent at 31:7-18.

“[T]he Federal Circuit has ruled that claims reciting common hardware to perform functions a human could not, such as a *scanner* to collect data, do not thereby negate the abstract nature of the claim.” *ICON Health & Fitness, Inc. v. Polar Electro Oy*, 243 F. Supp. 3d 1229,

1239 (D. Utah 2017), *aff'd*, 717 Fed. Appx. 1005 (Fed. Cir. 2018) (*citing Content Extraction and Transmission LLC v. Wells Fargo Bank, Nat. Ass'n*, 776 F.3d 1343, 1347 (Fed. Cir. 2014)).

Similarly, the specification describes no specialized “processor” or storage medium needed for the invention. Where, as here, a patent simply references generic existing technology that is “not even arguably inventive,” that is “insufficient to pass the test of an inventive concept in the application of an abstract idea.” *See Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1355 (Fed. Cir. 2016) (quotation marks omitted); *see also Alice*, 573 U.S. at 222 (stating that computer implementation of an abstract idea does not “supply the necessary inventive concept [where] the process [can] be ‘carried out in existing computers long in use.’”) Dr. Dempsey confirms that the Asserted System Claims add nothing new. As Dr. Dempsey explains:

Existing rTMS machines sold in the United States use processors to control the firing of the magnetic field. For example, the MagVenture R30 contains a processor which allows the user to set and administer various frequencies, field strengths, pulse trains, durations, and other characteristics of the rTMS therapy on the machine itself. This machine is also configured with a data port (a/k/a COM2) which allows it to be controlled by an external computer or processor.

Dempsey Dec. at ¶36. Thus, the generic components of the asserted system claims were already well-understood and conventional, and add no inventive concept “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.” *Mayo*, 566 U.S. at 72–73, 77–80.

VII. CONCLUSION

For the foregoing reasons, each asserted claim of the patents at issue is directed to unpatentable subject matter under 35 U.S.C. § 101, and summary judgment should be granted.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on 7 February 2025, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Henning Schmidt
Henning Schmidt